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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,396	07/10/2001	Keith D. Allen	R-359	9463
26619	7590	09/20/2005	EXAMINER	
JOHN E. BURKE GREENBERG TRAURIG LLP 1200 17TH STREET, SUITE 2400 DENVER, CO 80202			BERTOGLIO, VALARIE E	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/903,396	ALLEN, KEITH D.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Valarie Bertoglio	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 01 July 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 36-41,47 and 49-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 36-41,47,49-53 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 07/10/2001 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

**DETAILED ACTION**

Applicant's submission filed on 07/01/2005 has been entered. Claims 36-41 and 47 have been amended. Claims 42-46 and 48 have been cancelled. Claims 49-53 have been added. Claims 36-41,47 and 49-53 are pending and under consideration in the instant office action.

*Specification*

The amendment filed 07/01/2005 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention.

Applicant has amended the specification at page 9, paragraph 3 to incorporate US Provisional Application 60/084194. This reference is not considered new matter because the original specification incorporated USSN 08/971310 by reference, which was converted to the Provisional Application 60/084194. However, the additional references are considered new matter. The references include a second provisional application (60/084949), a utility application claiming priority to the two provisional applications (09/193,834) and a second utility application that is a continuation of the first utility application (09/885,816; published as US Patent 6,815,185). There is no evidence that these newly referenced applications were contemplated as being part of the original specification as an incorporation by reference. The reference to "U.S. Patent no. 6,815,185 issued November 9, 2004, which is based on U.S. Patent Application No. 09/885,816, filed June 19, 2001, which is a continuation of U.S. Patent Application No. 09/193,834, filed November 17, 1998, now abandoned, which claims priority to provisional application no. 60/084,949, filed on May 11, 1998, and provisional application no. 60/084,194, the disclosure of provisional application no. 60/084,194" should be deleted.

***Claim Objections***

The objection to claim 47 is maintained for reasons of record set forth at page 2 of the office action mailed 02/15/2005. Applicant's arguments have been considered and are not persuasive.

Applicant has traversed the objection of claim 47 regarding the recitation that a pseudopregnant mouse gives birth. Applicant refers to a published textbook setting using the terminology and asserts that the terminology would be clearly understood by one skilled in the art (see page 5, paragraph 4 of Applicant's Remarks). In response, the objection is maintained. Upon impregnation, the pseudopregnant mouse of the claim is no longer pseudopregnant. The clarity of references to pseudopregnant mice in a textbook has little weight in establishing that it is accepted in the art to call a pregnant mouse pseudopregnant. For the sake of clarity, Applicant should amend the claim to read, "wherein the resulting pregnant mouse gives birth to a chimeric mouse".

***Claim Rejections - 35 USC § 101/112***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

***Utility***

Definitions:

[from REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS; repeated from <http://www.uspto.gov/web/menu/utility.pdf>]

"Specific Utility" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention. For example, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be be

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considered to be *specific* in the absence of a disclosure of a specific DNA target. Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed.

"Substantial utility" - a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

- A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.
- B. A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. 101.)
- C. A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility".
- D. A method of making a material that itself has no specific, substantial, and credible utility.
- E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

See also the MPEP § 2107 - 2107.02.

Claims 36-41 and 47 remain rejected and claims 49-53 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. The rejection set forth on pages 2-7 of the previous office action mailed 03/08/2005 is maintained for reasons of record. Applicants arguments filed 07/01/2005 have been fully considered and are not persuasive.

The instant specification has discussed that the mice of the instant invention can be used as models of disease to screen for drug therapies and as a tool for studying the function of a gene encoding SEQ ID NO:1. As set forth in the previous office action, these uses fail to meet the standards of a specific, substantial and well-established utility required under 35 U.S.C. 101. In summary, the utilities provided by Applicant for the claimed mouse are not specific or substantial and therefore are not well established because the use of the mouse in screening for

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drugs to treat an unknown disease is not specific or substantial. The use for the claimed mouse in characterizing the function of a gene encoding SEQ ID NO:1 is not substantial. The teachings in the specification failed to characterize or define the role of the gene that correlates to the cDNA set forth by SEQ ID NO:1. Therefore, it cannot be determined without additional experimentation that the claimed gene and knockout mouse has a well-established use. The skilled artisan would not know how to use a mouse that exhibits the claimed phenotypes other than for further study of that mouse to determine a real world use. Further basis for this rejection is further set forth in the previous office action dated 03/08/2005 and in the guidelines above.

Applicant's arguments at pages 6-16 of the reply were addressed in the previous office action of 03/22/2005 at pages 3-7. Applicant has reiterated various aspect of their arguments and have provided additional arguments that are addressed below.

Applicant argues that the person of ordinary skill in the art would find the claimed invention useful for determining gene function (see page 11, Well-Established Utility, Applicant's remarks).

In response, such a use is neither specific nor substantial as set forth in the previous office action. To use the claimed mouse to study gene function amounts to no more than study of the invention itself. Further experimentation is required to determine that this use has real-world utility. Furthermore, use of the claimed knockout mouse to study gene function is not specific in that any knockout mouse can be used to study the function of the gene knocked out or any other gene. Furthermore, there is no evidence that the claimed mouse will provide insight into the function of the glucocorticoid induced receptor gene because not all knockout mice are effective

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in revealing gene function. Merely knocking out a gene is not sufficient to confer specific utility on a mouse.

Applicant has requested that the basis of the rejection be explained as it relates to "specific utility" (pages 11-12). In response, the use of the claimed mouse to study the function of the glucocorticoid induced receptor gene is not specific because any particular knockout mouse can be used to study the particular gene that has been knocked out. This is a general utility and is not specific. Furthermore, there is no evidence that the claimed mouse will provide insight into the function of the glucocorticoid induced receptor gene because not all knockout mice are effective in revealing gene function. Merely knocking out a gene is not sufficient to confer specific utility on a mouse.

Applicant argues that the expression of *lacZ* in the claimed mouse provides specific utility (page 12). Again, the utility of this mouse is not specific in that any mouse constructed with a *lacZ* gene inserted into any gene, can be used to the same extent as the claimed mouse to study expression of the disrupted gene. Applicant has taught no specific properties of this mouse to set forth any real-world use. Basic research, study of the invention itself, and further research to confirm a real-world use are not patentable utilities (see above). Furthermore, there is no evidence to support that the *lacZ* expression pattern mimics that of the endogenous glucocorticoid induced receptor gene. The specification teaches that the endogenous glucocorticoid receptor gene is expressed in lymphoid cells (see specification at page 2), however, expression of *lacZ* in these cells is not reported (see pages 52-53 of the specification).

Applicant argues that the claimed invention has substantial utility (pages 12-15). Applicant asserts that further research is not required to identify any use (page 13). In response, a

use can be found for any mouse. For example, a knockout mouse with a disruption in a transcriptionally silent gene with no phenotype at all can be used as snake food. This is not a real-world use and does not overcome the requirement for specific and substantial utility. Likewise, the lack of a real world use for the claimed invention and the necessity for addition research to identify or confirm such a use necessitates the rejection of the claimed invention as lacking substantial, and therefore, patentable utility.

Applicant also discloses the commercial use of the claimed mice and states that commercial use and acceptance is one important indication that the utility of an invention has been recognized by one of skill in the art (page 14 of Applicant's remarks). Applicant has submitted a declaration from Dr. Robert Driscoll stating that the mice have been sold to at least one large pharmaceutical company for the use of studying gene function and for human therapeutic drug development.

In response, the commercial use of the claimed mouse is not dispositive of the lack of a specific and substantial asserted utility in the original specification and does not provide evidence of a well-established use at the time the application was filed. Paragraph 4 of the declaration states that mice obtained from Deltagen are used for study of gene function and human therapeutic drug development. The declaration does not state that the claimed mouse is being used for any particular purpose. Despite this, as set forth above and in the previous office action mailed 03/08/2005, uses in study of gene function and human therapeutic drug development for an unspecified disease, are not specific or substantial. Applicant is reminded that the requirements under §101 and §112, 1<sup>st</sup> para. must be met at the time the application is filed. There is no evidence in the declaration that the companies are using the mouse for any use

identified in the specification. The discovery of an undisclosed use meeting these requirements after the application is filed does not satisfy the statutory requirements under either §101 or §112, 1<sup>st</sup> para. See *In re Kirk*, 153 USPQ 48, 52 (CCPA 1967); *In re Wright*, 27 USPQ2d 1510, 1514 (Fed. Cir. 1993). The declaration filed does not provide any evidence that the requirements of a specific and substantial use were met at the time of filing.

Applicant has referred to the principles set forth in *In re Brana* (see pages 15-17 of Applicant's remarks). Applicant asserts that the specification supports a use of the knockout mouse that is specific and substantial in light of the teaching of *In re Brana*.

In response, the fact pattern in *Brana* does not correlate to the fact pattern of the instant application. In *Brana*, the court addressed two separate issues, utility and enablement. The court held that the specification did, in fact, disclose a specific and substantial use for the compound, treating leukemia, and that this use was overlooked by the PTO in making the rejection under 101. The court observed that the claimed compound was similar in structure to compounds in the prior art that were useful in treating leukemia. The claimed compound behaved in a manner similar to that of the prior art in art accepted assays for anti-leukemic activity. Therefore, the specification enabled the use. The instant specification and the art of record fail to support such a patentable utility for the instant invention and therefore, the principles set forth in *In re Brana* do not apply to the instant invention.

*Enablement*

Claims 36-41 and 47 remain rejected and claims 49-53 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a

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specific or substantial utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 36-41 and 47 remain rejected and claims 49-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In addition to the reasons raised in the rejection made under 35 USC 101 for the specification failing to teach to use the claimed products and methods of making the claimed products, the claims further lack enablement for reasons of record set forth at pages 7-12 of the office action dated 03/08/2005.

Applicants' arguments filed 07/01/2005 have been fully considered and are not persuasive.

Applicant continues to maintain that the specification is enabling for the claimed mice because the claims encompass two possibilities, a heterozygous and a homozygous mouse having one or two null alleles, respectively (page 18) and the specification teaches how to make and use both of these embodiments.

In response, the claims are broad in terms of the genus of genetic backgrounds encompassed by the claims. As set forth in the office action dated 11/06/03 at pages 6-8, it was accepted in the art that behavioral phenotypes, such as those claimed, are highly variable due to the genetic background of the mice. The specification speaks directly to and exemplifies the art as the disclosed mice comprising identical gene disruptions in different genetic backgrounds have different phenotypes (see page 53, last paragraph –page 54). In fact, the specification even

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teaches that the discrepancy in the results obtained likely reflect differences in the genetic backgrounds (page 54, lines 13-15). This aspect of the rejection is not relevant to the number of null alleles the mice comprise as argued by Applicant. The claims have further embodiments where they encompass a genus of genetic backgrounds, one of which the specification teaches does not exhibit a particular phenotype while another genetic background does (see pages 53-54). These embodiments are the grounds for the instant rejection

The phenotypes of the claimed mice in genetic backgrounds other than that resulting from the use of 129/SvEv ES cells and C57 BL/6 mice wherein the F1N0 heterozygotes were backcrossed to C57BL/6, not intercrossed (see page 53, lines 17-21), would not predictably result in the phenotypes taught in the specification (claims 37-40) and, the broad genera of phenotypes, including wild-type, cannot be predictably obtained in any genetic background (claims 36,47 and 49-53 that fail to recite a phenotype).

The art at the time of filing held that phenotypic differences in knockout mice might stem from differences in genetic background because metabolic and behavioral phenotypes are known to be very sensitive to the genetic background and environmental factors [Hara et al, *Neuroscience Letters*, 380:239-242, 2005; Pearson, *Nature*, 415:8-9, 2002]. Silva teaches that mutations can have very different phenotypes in different backgrounds [*Neuron*, 19:755-759, 1997, specifically page 755, last full sentence of column 1]. The exact identity of the control mice are not taught by the specification but it is noted that even wild-type sibling mice differ in genetic background from mutant mice at loci that are linked to the gene disruption (see Silva at page 756, paragraph bridging columns). Therefore, it is not predictable that any mouse encompassed by the claims other than that specifically described in the specification in terms of

genetic background and observed phenotype would exhibit any of the phenotypes specifically or generically encompassed by the claims.

A new grounds of rejection based on the claim amendments is set forth below.

Claims 36-41,47 and 49-53 are not enabled because claim 36, as written, encompasses a disruption of a non-endogenous glucocorticoid-induced receptor gene, i.e. a transgenic mouse whose genome comprises a transgene encoded a null glucocorticoid-induced receptor gene. The specification teaches disruption of the endogenous glucocorticoid-induced receptor gene by homologous recombination. It does not teach a mouse whose genome comprises an exogenous transgene encoding a null glucocorticoid-induced receptor allele. It would be expected that a transgene encoding a null, nonfunctional glucocorticoid-induced receptor gene product would not exhibit any phenotypes as a result of the null allele but that any observable phenotypes would be due to the disruption of some endogenous gene at the site of transgene integration. The phenotype of such a mouse would be unpredictable both because the site of integration is random and unpredictable and because the phenotype of transgenic animals is generally unpredictable as described at pages 8-9 of the office action dated 03/12/2003. In light of the lack of guidance in the specification and the unpredictability of phenotype in transgenic mice known in the art, it would require undue experimentation to make and use the mouse whose genome comprises a transgene encoding a null glucocorticoid-induced receptor allele as broadly encompassed by the claims.

*New Matter*

The following new rejection is necessitated by the newly added claim 53.

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Claim 53 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

Claim 53 has been amended to recite that the null allele of the mouse of claim 47 further comprises a lacZ gene. This claim is unclear as set forth below under 35 USC 112, 2<sup>nd</sup> paragraph. For the purpose of examination under 35 USC 112, 1<sup>st</sup> paragraph, the claim is interpreted as being drawn to the mouse made by the method of claim 47 wherein the null glucocorticoid-induced receptor gene comprises a lacZ gene.

The specification does not provide support for the generic embodiments of the claim wherein the mouse, made using any genetic background and no selectable marker and a lacZ gene. The only teachings in the specification that teach the lacZ is Figure 2B showing the construct used to make the specific mice described at page 52, lines 6-9 and page 53, lines 16-21. There is no general description of the claimed genera of mice comprising a lacZ gene. The specification describes only two species of mouse comprising the lacZ gene and that the claims are directed to some characteristics of the species while leaving out other characteristics of the species. For example, the only mice described in the specification that comprises a lacZ gene was made using 129/SvEV or 129/Sv-+p+Mgf-SLJ/J ES cells with the chimeric offspring outcrossed to C57BL/6 followed by either intercross (both lines) or backcross (line derived from 129/SvEv. It appears that the lacZ was a promoterless lacZ placed upstream of the neomycin

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resistance genes. These limitations were omitted from the claim and are considered new matter as the use of lacZ was not generically taught in the specification and therefore was not described in any way other than in the context of these other specifications.

The specification does not describe a genus of knockout mice wherein the targeting construct contains a gene encoding lacZ. In contrast, the specification teaches, generically, that the targeting construct contains a positive selection marker between the targeting sequences. With respect to the lacZ gene, the specification does not mention, even in passing, a general feature of the claimed invention where the exogenous, inserted DNA encodes lacZ. Disclosure of a single species is rarely, if ever, sufficient to describe a broad genus, particularly when the specification fails to describe the features of that genus, even in passing. See, for example, *In re Shokal*, 113 USPQ 283 (CCPA 1957); *Purdue Pharma L.P. v. Faulding Inc.*, 56 USPQ2d 1481 (CAFC 2000).

MPEP 2163.06 notes, "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed. If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often

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necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure" (emphasis added).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 53 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 53 recites the limitation "the transgenic mouse of claim 47" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 47 is not drawn to a transgenic mouse but to methods of making a transgenic mouse. For the purpose of examination, claim 47 is interpreted as reading on the transgenic mouse made by the method of claim 47 wherein the null allele comprises a lacZ gene.

Claim 53 is further unclear because it recites "further comprising" when there is not prior limitation of the composition of the null allele.

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***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Valarie Bertoglio  
Examiner  
Art Unit 1632

*Scott D. Priebe*  
**SCOTT D. PRIEBE, PH.D**  
**PRIMARY EXAMINER**